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October 31, 2012

510(k) Summary

RE: Electrical and Portable Pressurized Infusion Pump

Summary prepared by:

Contact Person: **Tammy Mui**
Title: **Operations Manager**
Manufaxturer: **Mui Scientific, a Division of H&A Mui Enterprises**
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Trade name: **Pressurized Infusion Pump**
Common name: **Water-perfused motility pump**
Classification name: **Gastrointestinal motility system**

This 510(k) Summary is for the Pressurized Infusion Pump.

Indications for Use: The Pressurized Infusion Pump (Electrically Powered Models #PIP-4-4SS, PIP-4-6SS, PIP-4-8SS, PIP-4-12SS, and Portable Models #PIP-6-4SS, PIP-6-6SS, PIP-6-8SS, PIP-6-12SS, PIP-6-16SS, PIP-6-22SS, PIP-6-24SS, PIP-6-36SS) is intended to provide a regulated and channeled perfusate of water to a motility catheter to perform manometric motility studies along the gastrointestinal tract. The Pressurized Infusion Pump is intended to be used with a separate legally marketed compatible motility catheter and separate computerized gastrointestinal monitoring system.

These pressurized infusion pumps consist of an electrical compartment, a water chamber, a regulator and a set of gauges, and flow restrictors. The electrical compartment unit consists of a compressor motor, a pressure switch, a pressure gauge, and a drying cylinder. When turned on, the motor will compress air into the drying cylinder, which will remove the water by-product from the compression. The pressure switch will turn the motor off at 42psi (as displayed on the pressure gauge), and will restart it when the pressure drops to 18psi. For the Portable Pressurized Infusion Pump, an air hose connects the electrical unit to the main pump housing to deliver the pressurized air to the pump. The pressurized air will flow through a high pressure gauge (to display the pressure of the supplied compressed air), to a regulator (which will regulate the pressurized air down to 17psi), then a low pressure gauge

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(to display the pressure of the regulated air), to a water reservoir filled with sterilized irrigation water. The regulated air will push the water out of the water reservoir at a constant rate through resistors that will further reduce the water flow rate to 0.60mL/min before it travels through a pressure transducer to the motility catheter. At the proximal end of the motility catheter are female luers that connect to the top of the pressure transducers on the infusion pump. The water will flow through the entire length of the motility catheter to the distal end where the pressure ports are located. The motility catheter is then inserted into the patient and placed along the specific section of the gastrointestinal system being measured. With the regulated pressurized water flowing through the catheter at a constant rate, when the gut muscles contract, it will constrict the flow of water through the pressure ports, and the pressure change will be transmitted back through the water flow to the pressure transducer on the pressurized infusion pump, where the signal will be displayed onto the computer.

We are claiming this system to be substantially equivalent to the following predicates:

- Mui Scientific's Nitrogen gas model of the pressurized infusion pump

The Electrical and Portable pump versions are similar to this predicate in that they use pressure to push water from a water reservoir through resistors that further reduce the flow rate before passing through a motility catheter. The difference is the source of the pressure: compressed nitrogen gas in the predicate, and an air compressor motor in the Electrical and Portable pump models.

Bench tests were conducted with the Electrical and Portable Pressurized Infusion Pumps, comparing performance data with that of its predicates. With the systems on and perfusing, a pinch test was performed over each of the 8 pressure ports along the motility catheter, to mimic a muscle contraction. The pressure exerted was shown to equal the pressure measured and transmitted on the predicate pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter date: November 1, 2012

Mui Scientific
Division of H&A Mui Enterprises Inc.
% Ms. Tammy Mui
Operations Manager
145 Traders Blvd. East, Unit #34
MISSISSAUGA ON
CANADA L4Z 3L3

Re: K122294
Trade/Device Name: Pressurized Infusion Pump
Regulation Number: 21 CFR§ 876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: FFX
Dated: October 15, 2012
Received: October 19, 2012

Dear Ms. Mui:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122294

Device Name: Pressurized Infusion Pump

Indications For Use:

The Pressurized Infusion Pump (Electrically Powered Models #PIP-4-4SS, PIP-4-6SS, PIP-4-8SS, PIP-4-12SS, and Portable Models #PIP-6-4SS, PIP-6-6SS, PIP-6-8SS, PIP-6-12SS, PIP-6-16SS, PIP-6-22SS, PIP-6-24SS, PIP-6-36SS) is intended to provide a regulated and channeled perfusate of water to a motility catheter to perform manometric motility studies along the gastrointestinal tract. The Pressurized Infusion Pump is intended to be used with a separate legally marketed compatible motility catheter and separate computerized gastrointestinal monitoring system.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122294